

Appendix VIII: 510(k) Summary of Safety and Effectiveness**VacuFlash® Biopsy System****Company:**

BIP USA Inc.
345 Third Street, Suite 400
Niagara Falls, NY 14303

MAR 11 2003

Contact

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Date Prepared

03 December 2002

Name of Device

Trade Name: VacuFlash® Biopsy System
Classification Name: Biopsy Needle

Predicate Devices

Ethicon Mammotome® Hand Held 8 Gauge Probe
Ethicon Mammotome® Hand Held System
Ethicon Mammotome®
Suros ATEC® Vacuum Assisted Core Biopsy System

Device Description

The BIP VacuFlash® Biopsy System is a mechanical device that may be used with imaging guidance (such as ultrasound, X-Ray, stereotaxy, CT, or MR) to provide breast tissue samples for histologic examination with partial or complete removal of the imaged abnormality.

The VacuFlash® Biopsy System consists of three major components: a disposable trocar tipped needle with a vacuum cylinder, a disposable introducer with stylette, and a reusable device housing containing the control module, touch pad with control buttons and LEDs indicating device status, and vacuum/air pressure generators. The disposable needle/vacuum cylinder will be available in several different lengths. A battery recharger/table top stand is the only provided accessory. Mounting brackets to attach the VacuFlash® Biopsy System to the Fischer Mammotest® and to the Lorad stereotactic tables are optional accessories. In addition, brackets to attach the VacuFlash to the Siemens stereotactic mammography and to the Siemens MR Mammography Biopsy systems are available. Sterile bushings for the above devices, including CytoGuide stereotactic and GE DMR Mammography systems are also available.

The needle inner cannula incorporates a distal sampling window with sharpened edges. During the biopsy procedure, tissue is vacuum aspirated into the inner cannula and cut using both the sampling window edges and the rotating edge of the outer cannula. Once the needle is removed from the patient's body, the sampling window is opened and the specimen removed. Tissue samples may be collected in radial order so that when imaging guidance is used, sampling positions may be retrospectively correlated with the imaging display.

Intended Use

The BIP VacuFlash® Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Substantial Equivalence

The BIP VacuFlash® Biopsy System is substantially equivalent to the Mammotome® that was determined to be substantially equivalent on 28 March 1997 (K970565). The BIP VacuFlash® Biopsy System is also substantially equivalent to the Mammotome® Hand Held System that was determined to be substantially equivalent on 17 August 1999 (K991980) and the Mammotome® Hand Held 8 Gauge Probe that was determined to be substantially equivalent on 18 January 2001 (K003297). In addition, the VacuFlash® Biopsy System is also substantially equivalent to the Suros Surgical Systems ATEC® Vacuum Assisted Core Biopsy System that was determined to be substantially equivalent on 24 May 2001 (K010400).

The BIP VacuFlash® Biopsy System has similar indications for use and technological characteristics as the predicate devices. The patient contact components and component materials for obtaining core biopsy samples in both the new and predicate devices are equivalent. The packaging materials, packaging configuration, sterilization methods and sterility assurance level are also equivalent.

The hand-held or mounted biopsy device, used with or without imaging modalities, provides for the diagnostic removal of tissue with fluid management through a combination of vacuum and *radial cutting functions*. The proposed and predicate devices contain the same primary components to achieve these functions: a needle/probe, housing/handle/holster, and a control module.

In the proposed device, the housing contains the motor and control module as well as an integrated battery and vacuum/air pressure generation equipment. A touch pad is also integrated into the device with buttons for operational control and LED indicator lights provide feedback. The needle/probe and the device weigh approximately 14 oz. Integration of all components into the handle/housing makes the device portable and facilitates user and patient interface. The control module allows the VacuFlash® Biopsy System to provide semi-automatic and automatic modes of operation for *cutter advancement*, *cutter rotation*, and specimen retrieval. In addition, the variability of user interaction is minimized.

Preclinical testing confirms the quality of samples obtained with the BIP VacuFlash® Biopsy System is equivalent to those obtained with the predicate devices.

Based on the indications for use, technological characteristics and testing results, the BIP VacuFlash® Biopsy System does not raise significant new questions of safety and effectiveness.

Performance Data

Preclinical testing was performed to confirm the device performs as intended. Testing demonstrated satisfactory performance in breast tissue biopsy.



MAR 11 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Siegfried Gruchot
General Manager
BIP USA, Inc.
345 Third Street, Suite 400
Niagara Falls, New York 14303

Re: K024089
Trade/Device Name: VacuFlash Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: December 3, 2002
Received: December 11, 2002

Dear Mr. Gruchot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

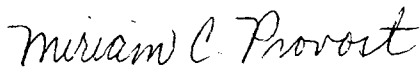
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K024089

Device Name: VacuFlash Biopsy System

Indications for Use:

The BIP VacuFlash® Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use _____

Per 21 CFR 801.109

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024089